

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

UNIVERSITY OF  
MASSACHUSETTS and CARMEL  
LABORATORIES, LLC,

Plaintiffs,

v.

L'ORÉAL USA, INC.,

Defendant.

C.A. No. 17-cv-868-CFC-SRF

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**PLAINTIFFS' MEMORANDUM OF LAW  
IN OPPOSITION TO L'ORÉAL'S MOTION FOR  
SUMMARY JUDGMENT OF INDEFINITENESS OF  
THE "SKIN ENHANCEMENT CLAIM LIMITATION"**

DATED: October 2, 2020

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## **I. NATURE AND STAGE OF THE PROCEEDINGS**

This is a patent infringement case. Trial is set for February 2021.

## **II. SUMMARY OF ARGUMENT**

L'Oréal's motion is its latest request to ignore the claim language in a tortured construction that has already been rejected. Months ago, this Court ordered claim 1 of each patent-in-suit discloses a "concentration" of adenosine, which is an amount "effective to enhance" the skin, recited as a specific numerical range in each asserted claim. L'Oréal's motion again turns the claim language on its head, arguing applying the claimed concentration is not applying the recited amount of adenosine to the dermal cells, and must instead result in "enhancement" each time the method is performed. The claims do not say that.

"Indefiniteness is a matter of claim construction, and the same principles that generally govern claim construction are applicable to determining whether allegedly indefinite claim language is subject to construction." *f'real Foods, LLC v. Hamilton Beach Brands, Inc.*, 388 F. Supp. 3d 362, 364 (D. Del. 2019) (Connolly, J.) (quoting *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1319 (Fed. Cir. 2008)). L'Oréal provides no support for its reassertion of a *Markman* position that has been discredited repeatedly. This Court already held that the "claim language and specification" of the patent provide "reasonable certainty" as to claim 1's meaning; it is not indefinite. *Exmark Mfg. Co. Inc. v. Briggs & Stratton Power Prod. Grp., LLC*, 879 F.3d 1332,

1345 (Fed. Cir. 2018). And even if L'Oréal could prevail on its renewed request to rewrite the language, its motion merely creates a factual dispute inappropriate for summary judgment.

### III. STATEMENT OF FACTS

The pertinent facts are set forth below.

### IV. ARGUMENT

#### A. L'Oréal's Motion Depends Upon Its Incorrect and Already-Rejected Claim Construction

Claim 1 of the '327 recites:

A method for enhancing the condition of unbroken skin of a mammal by reducing one or more of wrinkling, roughness, dryness, or laxity of the skin, without increasing dermal cell proliferation, *the method comprising topically applying to the skin* a composition comprising *a concentration of adenosine in an amount effective to enhance* the condition of the skin without increasing dermal cell proliferation, wherein *the adenosine concentration applied to the dermal cells is  $10^{-4} M$  to  $10^{-7} M$ .*

Ex. 1<sup>1</sup> (emphasis added); *see also* Ex. 2 ('513) (the concentration is “ $10^{-3} M$  to  $10^{-7} M$ ”).

L'Oréal argues that “a concentration of adenosine in an amount effective to enhance the condition of skin” is indefinite because it is not clear when

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<sup>1</sup> Citations to “Ex. \_\_\_\_” are to L'Oréal's exhibits. Citations to “App'xE\_\_\_\_” are to Plaintiffs' opposition appendix.

“enhancement” occurs, which is not even a step of the method. This Court already found this language to have a reasonably definite meaning, ordering, after “lengthy briefing” and an “hour-and-15-minutes worth of argument,” that “the plain language is plain and it’s unambiguous”:

We have here a method that includes topically applying to the skin . . . a composition that includes a concentration . . . of adenosine in an amount effective to enhance the condition of the skin. . . . *[T]he wherein clause is defining that the measurement ten to the negative 4M to ten to the negative 7M . . . is referring back to the concentration that is in an amount effective to enhance the condition of the skin without increasing dermal cell proliferation . . .* So I actually found this to be one of the cases where I thought it was very, very clear from the claim language itself . . . .

Ex. 33 at 56:19-58:2 (emphasis added).

L’Oréal asks for a do-over of the Court’s construction, but the language is still “quite clear,” *id.* at 58:25, and its reference to “a concentration of adenosine in an amount effective to enhance the condition of skin” does not—as L’Oréal argues—refer to skin that is “in fact” “enhanced,” D.I. 279 at 1, but “refer[s] back to” the **concentration**, which is adenosine of “ten to the negative 4M to ten to the negative 7M,” for ’327 claim 1.

L’Oréal’s motion depends on its rejected construction. Its indefiniteness argument is incorrect for the reasons this Court already considered:



**The claim language and the specification.** The Court’s construction is supported by the plain language of the claim, which teaches topical application of “*a concentration of adenosine in an amount effective to enhance* the condition of the skin.” Ex. 1 (emphasis added). The concentration’s “effective” amount is plainly “ $10^{-4}$  M to  $10^{-7}$  M,” in the ’327, which immediately follows. *Id.* Nowhere does the claim state that “enhancement” occurs as a step of the method.

The specification<sup>2</sup> confirms this. It explains that the methods include “topically administering” a “therapeutically effective amount of adenosine.” Ex. 1 at 1:56-57; *see also id.* at 1:50-51; 1:64-65; 2:4-5. That “therapeutically effective amount” is “preferably  $10^{-3}$  M to  $10^{-7}$  M [.]” This amount of adenosine is “effective” because its application “enhance[s] the condition of skin” by “stimulat[ing] DNA synthesis, increas[ing] protein synthesis, and increas[ing] cell size” in “human skin fibroblasts.” *Id.* at 1:37-41; *see also id.* at 2:38-40; 6:15-9:50 (describing experiments in which the effective concentration was applied to dermal cells, resulting in their enhancement); Ex. 33 at 57:13-14 (noting that “the dermal cells” are “part of the skin”).

L’Oréal provides no textual support for its request to rewrite the claimed methods such that “enhancement” must “in fact” occur, rather than—as the claims actually say—the recited concentration of adenosine is applied to dermal cells.

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<sup>2</sup> The ’327 and ’513 specifications are nearly identical. Plaintiffs cite to the ’327.

L'Oréal elides the claim language, divorcing the word “enhance” from its surroundings. L'Oréal points to specification passages that explain the method “*advantageously allows* for enhancement of skin condition,” which means a “noticeable decrease” in, for example, wrinkling. Ex. 1 at 2:35-48 (emphasis added). These disclosures do not define “a concentration of adenosine in an amount effective to enhance,” which is defined elsewhere. *See supra* p. 4. L'Oréal's cited disclosures explain what the methods *can be used for*, not what they *are*.

**The prosecution history.** Like in the *Markman* phase, where L'Oréal has no textual support for its construction, it relies instead on a strained reading of the prosecution history. But the prosecution history again supports Plaintiffs. *Cf.* Ex. 33 at 58:4-7 (“I don't think there has been any showing of any kind of clear redefinition of what the disputed terms mean in the prosecution history or in the written description.”); *see also Ecolab, Inc., v. FMC Corp.*, 569 F.3d 1335, 1342 (Fed. Cir. 2009) (holding that disclaimer must be “clear and unmistakable”).

In prosecution, applicants initially submitted claim 1, reciting “[a] method for enhancing the condition of non-diseased skin of a mammal, comprising topically applying a therapeutically effective amount of a composition comprising adenosine or an adenosine agonist to non-diseased skin of said mammal.” Ex. 24 at CARMEL LABS\_00000762. That claim was rejected as “vague because it is not clear as to enhance from what and to achieve what effect,” and the examiner requested

“clarification.” *Id.* at CARMEL LABS\_00000784. Applicants responded, “this phrase is not vague, because it is defined in the specification at page 3, lines 3-6,” *id.* at CARMEL LABS\_00000793, which recites that the method enhances by “topically administering a therapeutically effective amount of adenosine,” defined on the same page as “ $10^{-3}$  M to  $10^{-7}$  M,” *id.* at CARMEL LABS\_00000744. But “in the interests of moving this application towards allowance, and *not for any reason related to patentability*,” applicants added the requested clarification that the methods could be used for “reducing one or more of wrinkling, roughness, dryness, or laxity of the skin.” *Id.* at CARMEL LABS\_00000793 (emphasis added).

In short, applicants—consistent with the plain meaning—pointed to the effective concentration of adenosine that is applied to the dermal cells. Contrary to L’Oréal’s argument, *see* D.I. 279 at 9-10, applicants did not disclaim the plain meaning of the claim language. Even the requested amendment to add “what effect” the method is meant to “achieve” merely explains that it is *for* enhancing the skin, not that it must *actually result* in demonstrable skin enhancement as a claimed step.

Nor is L’Oréal aided by applicants’ discussion of the Cronstein reference in prosecution. L’Oréal claims applicants distinguished Cronstein as a “medical therapy,” whereas their invention purportedly results in “enhance[ment],” but L’Oréal grossly misportrays these passages. In fact, applicants distinguished Cronstein because Cronstein “limits his application of adenosine receptor agonists

to *open wounds such as burns*,” and “does not describe or suggest”—like applicants’ invention—“that adenosine should be applied to *unbroken skin*.” Ex. 24 at CARMEL LABS\_00000796 (emphasis added).

The intrinsic evidence shows that the language “a concentration of adenosine in an amount effective to enhance the condition of the skin” means exactly what it says: it is a concentration of the recited amount of adenosine, which the inventors determined is effective to enhance fibroblasts. The Court ordered this construction months ago. Where L’Oréal continues to fail to support its contorted interpretation of “very, very clear” language, its motion fails.<sup>3</sup>

#### **B. L’Oréal’s Bid to Shoehorn its Argument in Through the Preamble Fails**

The preamble of claim 1 of each patent-in-suit recites that it is a “method for enhancing the condition of unbroken skin of a mammal by reducing one or more of wrinkling, roughness, dryness, or laxity of the skin, without increasing dermal cell proliferation.” Exs. 1, 2. In its effort to redefine the claims, L’Oréal conflates the preamble with the language reciting “a concentration of adenosine in an amount

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<sup>3</sup> L’Oréal’s desire to ignore what happened in *Markman* includes even its *Daubert* motion related to Plaintiffs’ damages expert, stating the “asserted patents . . . claim the use of a specific ingredient (adenosine) in a topical composition,” D.I. 277 at 1, even though this Court rejected precisely that position, holding that the patents claim adenosine *applied to the dermal cells*, not the amount in a topical composition. See *Liqwd, Inc. v. L’Oreal USA, Inc.*, No. CV 17-14-JFB-SRF, 2019 WL 6840353 (D. Del. Dec. 16, 2019).

effective to enhance the condition of the skin,” calling them, together, the “enhance the condition of skin” limitation. D.I. 279 at 4. These are not the same. According to L’Oréal, the preamble also discloses a step in which skin is demonstrably enhanced. Like L’Oréal’s argument about the effective concentration, its reliance on the preamble flounders.

“[A] preamble is not limiting where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention.” *Catalina Mktg. Int’l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (quotations omitted). “Such a preamble does not limit the scope of the claim ‘unless the preamble provides antecedents for ensuing claim terms and limits the claim accordingly.’” *Applied Sci. & Tech., Inc. v. Advanced Energy Indus., Inc.*, 204 F. Supp. 2d 712, 717 (D. Del. 2002) (quoting *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1350 (Fed. Cir. 1998)).

L’Oréal does not argue the preamble provides antecedent basis, nor could it, where the claims recite structurally complete and unambiguous inventions. *See* Ex. 33 at 56:19-58:2; App’xE0000023 (“[T]he meaning of claim 1 is clear: adenosine is first topically applied to the epidermal layer of the skin and, only after it penetrates this outer skin layer, is a specific concentration ( $10^{-4}$  M to  $10^{-7}$  M) of the adenosine ‘applied’ to the dermal cells.”); *see also Arctic Cat Inc. v. GEP Power Prod., Inc.*, 919 F.3d 1320, 1329 (Fed. Cir. 2019) (the claim body is “a structurally complete

invention” where “deletion of the disputed phrase from the preamble would not affect the structural definition or operation of the invention itself”) (citations and alterations omitted).

Instead, L’Oréal points again to the prosecution history, discussed above, where applicants, in response to the examiner’s request to provide “clarification” as to “what effect” the method will have, explained it will “reduce one or more of wrinkling, roughness, dryness, or laxity of the skin.” *See supra* pp. 6-7. Applicants provided this “in the interests of moving this application towards allowance, and not for any reason related to patentability.” *See id.* Where, like here, references to the preamble in “the prosecution history appear to simply recite ‘benefits or features’ of the claimed invention” and there is no “clear reliance on those benefits or features as patentably significant,” the preamble “adds nothing” and “cannot be considered to give life, meaning, and vitality” to the claim. *Intirtool, Ltd. v. Texar Corp.*, 369 F.3d 1289, 1296 (Fed. Cir. 2004). L’Oréal’s reliance on Cronstein is likewise infirm. *See supra* pp. 6-7; *Honeywell Int’l, Inc. v. Nikon Corp.*, 589 F. Supp. 2d 433, 438–39 (D. Del. 2008), *supplemented*, 642 F. Supp. 2d 322 (D. Del. 2009) (where “the patentees at no point made any concrete statement distinguishing” their invention “from the prior art” on the basis of the preamble, there is no “clear and unmistakable disavowal of claim scope”).

Even “where a preamble is limiting”—which L’Oréal cannot support—the “preamble may be fairly read to describe ‘the environment’ rather than additional steps of the claimed method[.]” *Info. Prot. v. Symantec Corp.*, No. 2:08-CV-484, 2011 WL 13136605, at \*5 (E.D. Tex. Nov. 14, 2011), *on reconsideration in part sub nom. Info. Prot. & Authentication of Texas v. Symantec Corp.*, No. 2:08-CV-484, 2012 WL 12902780 (E.D. Tex. Mar. 16, 2012) (quoting *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1309 (Fed. Cir. 2011)). Here, the preamble’s language reciting “a method for enhancing the condition of unbroken skin of a mammal” cannot reasonably be interpreted to provide an additional step in which skin is “enhanc[ed].”

Grasping to find some support, L’Oréal resorts to implying that Plaintiffs agreed with L’Oréal’s construction during discovery. *See* D.I. 279 at 11. Not so. After learning of L’Oréal’s indefiniteness argument, Plaintiffs requested the parties submit that dispute to the Court to resolve during claim construction proceedings, but L’Oréal refused. App’x0000009-15. When L’Oréal served an interrogatory asking for Plaintiffs’ validity contentions, Plaintiffs responded that L’Oréal is “mistaken insofar as it bases its invalidity arguments on non-limiting language found in the preamble; these disclosures are not claim elements.” App’xE0000005.

L’Oréal’s claim construction, and therefore its motion, fails.

**C. Summary Judgment Must be Denied Even Under L'Oréal's Construction**

Even if L'Oréal were to somehow prevail in its construction, its motion fails.

L'Oréal argues the non-existent “enhancing” limitation(s) are indefinite because different “parameters or grading scales” may be used to determine whether skin has been “enhanced” and could “produce conflicting results.” D.I. 279 at 5-6. As a threshold matter, that a witness “assume[s]” it’s “a possibility” conflicting results might result, *see* D.I. 279 at 8, cannot support L'Oréal’s burden to show, by clear and convincing evidence, that no reasonable jury could support Plaintiffs. That is particularly true where the patents-in-suit recite that “[m]ethods of measuring improvements in skin condition are well known in the art,” and identifies one such “[o]bjective method[,]” “skin topography measurements,” in which “silicone rubber replicas are made of a small area of skin,” which “capture fine lines and wrinkles” and are then “analyzed using computerized digital image processing to provide an objective measurement of the skin’s topography.” Ex. 1 at 5:44-6:4 (“A statistically significant decline (e.g.,  $P < 0.05$ ) in Ra and Rz values in skin treated with an adenosine or an adenosine analog compared to untreated skin indicates an enhancement of skin condition.”). Plaintiffs’ expert opined that a POSITA reading the specification will understand that skin has been “enhanced” with adenosine based on such “digital skin topography measurements.” Ex. 12 ¶ 186; *see also f’real foods, LLC v. Hamilton Beach Brands, Inc.*, No. CV 16-41-CFC, 2019 WL 1648411,



at \*2 (D. Del. Apr. 16, 2019) (Connolly, J.) (denying MSJ of indefiniteness based on expert testimony that “create[d] a genuine dispute of material fact about whether the . . . limitation is clear enough to a person of skill in the art”).

L’Oréal provides no evidence that “conflicting results” will arise from digital skin topography measurements such that the claim language would lack definite meaning to a POSITA reading the specification. *See Cephalon, Inc. v. Slayback Pharma Ltd. Liab. Co.*, No. CV 17-1154-CFC, 2020 WL 1983730, at \*20 (D. Del. Apr. 27, 2020) (Connolly, J.) (denying MSJ of indefiniteness where “the patents provide a POSITA with a method for measuring”). Indeed, L’Oréal frequently makes claims about its products’ ability to enhance the skin, *see e.g.* App’xE0000030-33, confirming its scientists find it reasonably definite to determine when skin has been enhanced.

## **V. CONCLUSION**

For the reasons set forth above, Plaintiffs respectfully request the Court deny L’Oréal’s motion.

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**CERTIFICATION OF COMPLIANCE**

The foregoing document complies with the type-volume limitation of this Court's March 2, 2020 form Scheduling Order For All Cases where Infringement is Alleged. The text of this brief, including footnotes, was prepared in Times New Roman, 14 point. According to the word processing system used to prepare it, the brief contains 2,772 words, excluding the case caption, signature block, table of contents and table of authorities.

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